Songha Night Sugar-Coated Tablets/ Dragées Information for patients Information destinée aux patients

Carefully read this package insert. It contains important information.
You have received this drug either with a doctor's prescription for your personal use or by the pharmacist without a medical prescription.

So, in brider to obtain the greatest benefit from this medication, you should take it as described in this package insert or as advised by your physician or your pharmacist. Keep this package insert as you may wish to read it again or refer to it later on.

Songha[™] Night

Sugar-Coated Tablets

Herbal medicine

Properties and Indications

SONGHA NIGHT is a medicine based on herbal principles. Its active constituents are extracts of valerian roots and melissa leaves, which are regarded as mild sedatives. SONGHA NIGHT is used when there is difficulty in sleeping.

Advice

If the trouble lasts for more than a month, consult your doctor. Songha Night contains glucose and saccharose (402.7 mg of carbohydrate per coated tablet, which are equivalent to 0.03 carbohydrate units).

Contraindications and Precautions

SONGHA NIGHT should not be used if you are known to be hypersensitive to one of its constituents (see Composition).

Inform your doctor or pharmacist if

- you are suffering from other

- diseases,
 you have allergies or
- you take other drugs (including drugs you have bought by yourself!).

Pregnancy and Lactation

Based on the experience gained so far with the product, no risk for the unborn child is known when the medication is taken at the recommended dosage.

However, systematic scientific investigations have never been carried out.

As a precaution, you should avoid taking medicines during pregnancy and lactation or you should ask for advice from your physician or your pharmacist.

Dosage and Administration

Adults and children aged 12 years and above:

If there is difficulty in sleeping, swallow a single dose of 2-3 coated tablets, whole, with a little water between half an hour and one hour before going to bed.

SONGHA NIGHT should only be given to children aged 4 to 12 years when prescribed by the doctor.

Not suitable for young children (under 4 years of age).

Follow the dose given in the package insert or prescribed by a doctor. If you think the effect of the medicine is too week or too strong, you should speak to your doctor or your pharmacist.

Side effects

When SONGHA NIGHT is used as directed, no side effects have so far been observed.

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faltergic symptoms (skin rashes)
should occur, the medicine must be
discontinued and, if necessary, a doctor
consulted. If you do notice any side
effects, you should inform your doctor
or your pharmacist.

Storage conditions

SONGHA NIGHT should be kept in a dry place at room temperature [15-25°C], out of reach of children. The medicine must only be used up to the date shown by «EXP» on the pack. Further information is available from your doctor or pharmacist.

Composition

Each coated tablet contains: Dry extract 120.0 mg of valerian root (drug-extract ratio 3-6:1); Dry extract 80.0 mg of melissa leaves (drug-extract ratio 4-6:1); Excipients: Cellulose microcristalline; Silica, colloidal anhydrous; Glucose, liquid, spray-dried; Sodium starch glycolate, type A; Magnesium stearate; Sucrose; Talc; Acacia, spray-dried; Titanium dioxide; Macrogol 6000; Carnauba wax; Indigocarmine (85%)

Packages

In pharmacies and drugstores, without a medical prescription. Blister packs of 30 and 60 coated tablets.

Manufactured by Wiewelhove GmbH, Ibbenbüren - Gemany for Ginsana SA, Via Mulini 6934 Bioggio/Switzerland

This package insert was last checked by the Swiss drug regulatory authority (Swissmedic) in December 2003.